# SENATE BILL No. 329

**Introduced by Senator Cedillo**

February 16, 2005

An act to add Article 7 (commencing with Section 111657) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to drugs.

LEGISLATIVE COUNSEL'S DIGEST

SB 329, as introduced, Cedillo. California Prescription Drug Safety and Effectiveness Commission.

The Sherman Food, Drug and Cosmetics Law provides for the regulation of the processing, labeling, advertising, and sale of food, drugs, and cosmetics under the administration of the State Department of Health Services. A violation of these provisions is a crime.

This bill would establish the California Prescription Drug Safety and Effectiveness Commission within the California Health and Human Services Agency. The bill would prescribe the composition of the commission, how the members will be appointed, the terms of commissioners, and duties of the commission related to providing Californians with information on the safety and effectiveness of prescription drugs via an Internet Web site. The bill would require the commission to request assistance from a unit of the University of California.

The bill would provide that members of the commission and members of expert panels, when engaged in duties relating to commission or panel membership, are exempt from criminal sanctions under the Sherman Food, Drug and Cosmetics Law.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

*The people of the State of California do enact as follows:*

SECTION 1. The Legislature finds all of the following:

(a) There are significant safety problems associated with California's prescription drug supply.

(b) Californians do not have reliable central repository of information about prescription drug safety and effectiveness.

(c) California physicians and other prescribers could benefit from a reliable central repository of information about prescription drug safety and effectiveness.

(d) The Oregon Drug Effectiveness Review Project is developing information that could be used for a central repository of information about prescription drug safety and effectiveness.

(e) The California Health Care Foundation is developing information that could be used for a central repository of information about prescription drug safety and effectiveness.

(f) Safer and more effective prescription drugs within a class can also be among the less expensive prescription drugs within that class, meaning that a reliable central repository of information about prescription drug safety and effectiveness would create opportunities for prescription drug cost savings.

SEC. 2. Article 7 (commencing with Section 111657) is added to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 7. Prescription Drug Safety and Effectiveness

111657. For purposes of this article, the following terms have the following meanings:

(a) "Commission" means the California Prescription Drug Safety and Effectiveness Commission.

(b) "Evidence–based research" means prescription drug research in which the drugs in question have been administered to experimental and control groups and the subsequent effect of the drugs has been observed through those groups.

(c) "Systematically reviewed" means review of evidence–based research that has been selected based on preset standards.

111657.1. (a) There shall be a California Prescription Drug Safety and Effectiveness Commission within the California Health and Human Services Agency.

(b) The commission shall have nine members as follows:

(1) Three physicians; one who represents a nonprofit of public health system, and two employed by a school of pharmacy with the University of California system.

(2) Three pharmacists; one who represents a nonprofit of public health system, and two employed by a school of pharmacy with the University of California system.

(3) Three public interest representatives; one who is employed by a health education program within the California State University system, one who represents an organization that assists Medicare beneficiaries, and one who represents a community clinic or county health system.

(c) For each category of commission member described in subdivision (b), the Speaker of the Assembly, the President pro Tempore of the Senate, and the Governor shall each appoint one member. In making those appointments, professional and other interested organizations shall be consulted.

(d) The term of each commission member shall be three years, with first terms commencing January 1, 2006.

(e) The commission shall elect a chair, and all members shall serve without compensation, but be reimbursed for expenses incurred in the performance of their duties.

(f) The commission may establish expert panels on different therapeutic classes of drugs. The members of the panels shall be appointed by the chairperson, subject to the approval of a majority of the commission. At least one member of the commission shall serve on each panel. The panels shall meet in public in various locations around the state where public testimony is encouraged. The recommendations of the panels shall be presented to the full commission in a public hearing.

(g) No one shall be appointed to this commission or to an expert panel who has had a direct relationship with a pharmaceutical business within the previous 12–month period, including stock ownership, mutual funds that are specifically focused on pharmaceuticals, research support, salary, support of medical fellowships or educational endeavors, or honoraria for participating in speaker forums.

(h) Members of the commission and of expert panels shall disclose any economic interest they had in the pharmaceutical industry in the three years prior to the appointment. Economic interests include stock ownership, mutual funds that are specifically focused on pharmaceuticals, research support, salary, support of medical fellowships or educational endeavors, or honoraria for participating in speaker forums. All economic interests shall be disclosed, kept on file with the commission, and made available to the public upon request. Participating or voting on any matter affecting an entity in which a member has an undisclosed economic interest shall result in dismissal from the commission.

111657.2. (a) The commission shall do all of the following to provide Californians with information on the safety and effectiveness of prescription drugs:

(1) Establish a central repository of information about the safety and effectiveness of prescription drugs.

(2) Disseminate information to Californians through an Internet Web site.

(3) Assure that the dissemination of information is done in a culturally competent manner.

(4) In selecting therapeutic classes of drugs about which to develop information, focus on therapeutic classes about which there are particular safety concerns.

(5) Request a unit of the University of California to provide assistance. The unit shall be reimbursed for expenses incurred in the performance of any assistance.

(6) Rely on systematically reviewed evidence–based research.

(b) The commission shall have the authority to review the formularies of all state–funded programs for utilization of its information on the safety and effectiveness of prescription drugs.

(c) The commission shall not accept funds from pharmaceutical manufacturers or organizations funded by pharmaceutical manufacturers.

(d) Units of the University of California that provide assistance to the commission may solicit funds to implement this article.

111657.3. Members of the commission and members of panels established pursuant to subdivision (f) of Section 111657.1 shall not be considered persons for purposes of Section

111825 when engaged in duties relating to commission or panel membership.

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